

Exhibit 5



Advanced Integrative Medical Science Institute
2825 Eastlake Ave E, STE 115
Seattle, WA 98102

April 13, 2022

Anne Milgram, Administrator
Drug Enforcement Administration
Attn: Administrator
8701 Morrisette Drive
Springfield, VA 22152

Re: *Rulemaking petition to reclassify psilocybin from a Schedule I controlled substance to a Schedule II controlled substance*

Dear Administrator Milgram:

On February 2, 2022, Petitioners submitted a rescheduling petition to reclassify psilocybin from a Schedule I to a Schedule II controlled substance. More than two months later and the agency has not informed Petitioners whether their petition has been accepted for filing.

DEA's regulations provide that "[w]ithin a reasonable period of time after receipt of [a rescheduling petition], the Administrator shall notify the petitioner of his acceptance or nonacceptance of the petition, and if not accepted, the reason therefor." 21 C.F.R. § 1308.43(c). It further explains that once a petition accepted for filing, it "may be denied by the Administrator within a reasonable period of time thereafter if he finds the grounds upon which the petitioner relies are not sufficient to justify the initiation of proceedings." *Id.* Therefore, acceptance for filing does not mean that the agency has decided on the petition. Rather, it is a ministerial step that means that the agency received the petition and accepted it. And once accepted, the agency typically provides the public notice of acceptance.

Accepting a petition is a rote task that should not take DEA more than ten weeks to complete. Indeed, under the original regulations accompanying the CSA in the early 1970s, accepting petitions never took more than two months:

- On October 5, 1971, the the Bureau of Narcotic and Dangerous Drugs (BNDD) (predecessor agency to DEA) received a rescheduling petition from a student at Georgetown University and six other persons to transfer injectable liquids containing Pentazocine to Schedule III. By a letter dated October 28, 1973, BNDD notified the petitioner that the petition has been accepted for filing according to agency regulation. 36 Fed. Reg. 21527 (October 28, 1971).
- On March 8, 1972, BNDD received a petition from co-Directors of the Task Force on Drug Abuse and four other persons to transfer amobarbital, secobarbital, pentobarbital, and glutethimide from Schedule III to Schedule II. By a letter dated May 5, 1972, BNDD notified the petitioner that the petition has been accepted for filing according to agency regulation. 37 Fed. Reg. 9500 (May 11, 1972).

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- On April 11, 1972, BNDD received a rescheduling petition from pharmaceutical manufacturer Hexagon Laboratories, Inc., to remove levorotatory isomer of methamphetamine from Schedule II. By a letter dated June 27, 1973, BNDD notified the petitioner that the petition has been accepted for filing according to agency regulation. 37 Fed. Reg. 13352 (June 28, 1972).
- On April 4, 1973, BNDD received a rescheduling petition from pharmaceutical company A.H. Robins to initiate proceedings to transfer pholcodine to schedule II, III, or V of the CSA. By letter dated April 27, 1973, BNDD notified the petitioner that the petition has been accepted for filing according to agency regulation. 38 Fed. Reg. 11473 (May 8, 1973).

This shows that around the time of CSA's enactment under its original regulations, a reasonable amount of time to notify a petitioner of acceptance was measured in weeks, not months. We see no reason why, in 2022, a reasonable amount of time is any longer.

We are therefore concerned that DEA has yet to notify Petitioners whether it has accepted their petition. As we noted in the rescheduling petition, prompt processing is needed under the circumstances and exigencies presented in *AIMS v. Garland*, 21-70544 (9th Cir. Jan. 31, 2022) and noted in our rescheduling petition. In particular, as Dr. Volkow, the director of the National Institute on Drug Abuse (NIDA) recently explained, the barriers and stigma associated with a schedule I classification are significant and current schedule I status holds back scientific research. In short, this rescheduling petition—and DEA's delay—directly impact public health.

Petitioners again request that DEA promptly notify them of acceptance or non-acceptance of the rescheduling petition, and in no event later than thirty (30) days from this correspondence. Petitioners again request that the agency publish a notice in the Federal Register and open a public docket to enable comments on the proposed rule.

Finally, Petitioners additionally request the agency include this correspondence in the administrative record for Petitioners' rescheduling petition.

Respectfully submitted,

Petitioners:

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